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## **II. Rejection Under 35 U.S.C. § 112**

Claim 34 stands rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Insofar as it may be applied against the present claim, this rejection is respectfully traversed.

Claim 34 has been amended as suggested by the Examiner to overcome the rejection under 35 U.S.C. §112. When read in light of the specification, Applicants submit that the amendment of claim 34 does not narrow the claim with regard to the claimed dietary supplement compositions. Accordingly, it is respectfully requested that the rejection of claim 34 under 35 U.S.C. §112, second paragraph, be withdrawn.

## **III. Rejections Under 35 U.S.C. § 102(b)**

Claims 1, 6, 16 and 22 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,229,118 to Campbell (hereafter referred to as Campbell '118) and U.S. Patent No. 4,871,557 to Linscott (hereafter referred to as Linscott '557). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Campbell '118 and Linscott '557 must disclose all of the elements of claims 1, 6, 16 and 22 to sustain these rejections. Applicants respectfully traverse these rejections on the following grounds.

Campbell '118 discloses an animal feed and water additive prepared from seaweed. Campbell '118, however, also discloses that the additive includes formaldehyde as a preservative.

Linscott '557 discloses a granola bar with supplemental fiber such as apple pectin, gum arabic, gum ghatti and guar gum. Linscott '557, however, does not disclose that the apple pectin, gum arabic, gum ghatti or guar gum are treated in any manner to make the constituent saccharides of such fibers bioavailable as monosaccharides.

As noted in Exhibit A attached hereto which concerns certain technical information regarding water soluble gums such as gum arabic, gum ghatti and guar gum, "[g]ums do not metabolize in the body and thus do not add to caloric count." In other words, unless the fibers disclosed in Linscott '557 are treated in some manner, the constituent saccharides of such fibers are not bioavailable as monosaccharides and certainly have no nutritional effect.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim". Claims 1 and 22 recite, in part, a dietary supplement composition comprising at least six saccharides in which the composition is

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preservative-free and the saccharides are bioavailable as monosaccharides. As noted above, Campbell '118 fails to disclose or suggest a preservative-free composition and Linscott '557 fails to disclose or suggest a composition in which the saccharides are bioavailable as monosaccharides as required by MPEP § 2131. Therefore, claims 1 and 22 as well as claims 6 and 16 which depend therefrom are allowable over Campbell '118 and Linscott '557. For the foregoing reasons it is requested that the rejection of claims 1, 6, 16 and 22 over Campbell '118 and Linscott '557 be withdrawn.

Claims 1 and 22 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,021,560 to Montreuil et al. (hereafter Montreuil '560). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Montreuil '560 must disclose all of the elements of claims 1 and 22 to sustain this rejection. Applicants respectfully traverse this rejection on the following grounds.

Montreuil '560 discloses a glycoprotein extracted from Keyhole Limpet hemocyanin in which the glucidic fraction represents 5 to 5.25% of the glycoprotein molecule and the glucidic fraction includes mannose, galactose, fucose, glucose, xylose, N-acetylglucosamine and N-acetylgalactosamine.

Montreuil '560, however, similar to Linscott '557, does not disclose or suggest treating the glycoprotein in some manner to make the constituent saccharides bioavailable as monosaccharides.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim". Claims 1 and 22 recite, in part, a dietary supplement composition comprising at least six saccharides in which the saccharides are bioavailable as monosaccharides. Montreuil '560 fails to disclose or suggest this element as required by MPEP § 2131. Therefore, claims 1 and 22 are allowable over Montreuil '560. For the foregoing reasons it is requested that the rejection of claims 1 and 22 over Montreuil '560 be withdrawn.

Claim 40 stands rejected under 35 U.S.C. §102(b) over Citkowitz, Developmental Biology 27, 494-503 (1977) (hereafter Citkowitz) or Ortega U.S. Patent No. 3,947,601 (hereafter Ortega '601). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Citkowitz or Ortega '601 must disclose all of the

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elements of the claim to sustain these rejections. Applicants respectfully traverse these rejections on the following grounds.

According to Citkowitz an analysis of the hyaline layer of sea urchin embryos reveals that the hyaline layer is 2-3% carbohydrate and that the carbohydrate portion includes: fucose, xylose, mannose, galactose, glucose, N-acetylglucosamine, N-acetylgalactosamine and N-acetylneuraminic acid.

Ortega '601 discloses a food for fish and invertebrates which is compatible with a closed circuit salt water aquarium that includes broken sea urchin eggs.

However, similar to Linscott '557, neither Citkowitz nor Ortega '601 disclose treating the hyaline layer or the sea urchin eggs to make the saccharides bioavailable as monosaccharides.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim". Claim 40 recites, in part, a dietary supplement composition comprising at least six saccharides in which the saccharides are bioavailable as monosaccharides. Both Citkowitz and Ortega '601 fail to disclose or suggest this element as required by MPEP § 2131. Therefore, claim 40 is allowable over either or both Citkowitz and Ortega '601. For the foregoing reasons it is requested that the rejection of claim 40 over Citkowitz or Ortega '601 be withdrawn.

#### **IV. Rejections Under 35 U.S.C. § 103(a)**

Claims 1, 6, 7, 11, 16, 22 and 27-30 stand rejected under 35 U.S.C. §103(a) over Campbell '118 and Linscott '557 in view of U.S. Patent No. 3,890,438 to Cayen et al. (hereafter Cayen '438) and U.S. Patent No. 4,260,603 to Pegel et al. (hereafter Pegel '603). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Cayen '438 discloses pharmaceutical compositions for lowering blood cholesterol that include a mixture of diosgenin or a related diosgenin derivative and a 4-substituted phenoxyisobutyric acid or an ester or salt thereof. Cayen '438 discloses that suitable pharmaceutical formulations include tablets comprising: (a) the above-noted compositions, (b) known pharmaceutical carriers and excipients such as starch, sugars and lubricants, suspensions or syrups comprising the above-noted compositions, and (c) suspending agents such as water soluble gums.

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Contrary to the claimed dietary supplement compositions, however, Cayen '438 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

Pegel '603 discloses a medicament having prostaglandin-synthetase inhibiting activity. The medicament is disclosed to contain as an active principle sterolglycosides and/or their esters and/or spiroketal steroid glycosides and/or esters thereof. Contrary to the Office action, Pegel discloses at Column 5, lines 1-38, a process for the production of sitosterol -  $\beta$  - D - glucoside not a sitosterol -  $\beta$  - glucoside of diosgenin. Also, in contrast to the claimed dietary supplement compositions, Pegel '603 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on Campbell '118, Linscott '557, Cayen '438 and Pegel '603 for the following reasons.

As discussed above, Campbell '118 and Linscott '557 do not disclose or suggest the subject matter of claims 1 and 22. Specifically, neither Campbell '118 nor Linscott '557 disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides. Therefore, since claims 6, 7, 11, 16 and 27-30 include the subject matter of either claim 1 or 22, neither Campbell '118 nor Linscott '557 discloses or suggests the subject matter of claims 6, 7, 11, 16 and 27-30.

Neither Cayen '438 nor Pegel '603 supplies the deficiencies of Campbell '118 or Linscott '557 with respect to claims 1, 6, 7, 11, 16, 22 and 27-30. Thus, the combination of Cayen '438 and Pegel '603 with Campbell '118 and Linscott '557 fails to meet the standard presented by MPEP § 2143 which, as stated above, requires that the combined prior art references must teach or suggest all the claim limitations to establish a prima facie case of obviousness.

Furthermore, MPEP § 2143.01 provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Specifically, Cambell '118 is directed to an animal

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feed and water additive, Linscott '557 is directed to a granola bar with supplemental dietary fiber, Cayen '438 is directed to compositions for reducing blood cholesterol and Pegel '603 is directed to a sterol glycoside with activity as a prostaglandin synthetase inhibitor. Each reference addresses a different matter and one of ordinary skill in the art would have no reason or motivation to combine any of such references, much less all four of them. Therefore, there is no basis for the combination of Campbell '118, Linscott '557, Cayen '438 and Pegel '603, and it is respectfully submitted that the combination is improper. For the foregoing reasons, it is respectfully requested that the rejection of claims 1, 6, 7, 11, 16, 22 and 27-30 under 35 U.S.C. §103(a) over Campbell '118 and Linscott '557 in view of Cayen '438 and Pegel '603 be withdrawn.

Claims 1, 6-17, 22 and 27-36 stand rejected under 35 U.S.C. §103(a) over Campbell '118, Linscott '557, Cayen '438 and Pegel '603 in view of U.S. Patent No. 5,202,122 to Graves (hereafter Graves '122), Prescription For Nutritional Healing by Balch et al. (hereafter Balch), U.S. Patent No. 5,612,039 to Policappelli et al. (hereafter Policappelli '039), U.S. Patent No. 4,466,958 to Morrison (hereafter Morrison '958) and U.S. Patent No. 5,827,526 to Dohnalek et al. (hereafter Dohnalek '526). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Graves '122 discloses a process for enhancing the natural bile acid binding capacity of edible pulp material, which is also referred to as dietary fiber. Graves '122 discloses that the major constituents of dietary fiber include cellulose, hemicellulose, lignin and pectin. Graves '122 also discloses at column 6, lines 37-42 that pectin comprises the neutral sugars D-galactose, L-arabinose, D-xylose and L-fucose.

Contrary to the claimed dietary supplement compositions, however, Graves '122 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

The Balch reference consists of several extracts from a work entitled "Prescription for Nutritional Healing: A Practical A to Z Reference to Drug-Free Remedies Using Vitamins, Minerals, Herbs & Food Supplements." The Balch reference appears to be a general guide to the bodily function and source of a multitude of vitamins, herbs and food supplements. Balch indeed discloses that vitamins are essential to life and that every living cell on the planet depends on

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minerals for proper function and structure, however, Balch does not attribute such a lofty status to the antioxidant melatonin. Furthermore, in contrast to the claimed dietary supplement compositions, Balch does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

Policappelli '039 discloses a dietary supplement composition that includes herbal extracts combined with glucomannan or galactomannan.

Contrary to the claimed dietary supplement compositions, however, Policappelli '039 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

Morrison '958 discloses a food supplement that includes soy lecithin.

Contrary to the claimed dietary supplement compositions, however, Morrison '958 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

Dohnalek '526 discloses the use of fructooligosaccharides that occur in plants such as onions, asparagus, and tomatoes to prevent gastrointestinal infections and to reduce duration of diarrhea in humans.

Contrary to the claimed dietary supplement compositions, however, Dohnalek '526 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on Campbell '118, Linscott '557, Cayen '438, Pegel '603, Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 for the following reasons.

As discussed above, Campbell '118, Linscott '557, Cayen '438 and Pegel '603 do not disclose or suggest the subject matter of claims 1 and 22. Specifically, none of Campbell '118, Linscott '557, Cayen '438 or Pegel '603 disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as

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monosaccharides. Therefore, since claims 6-17 and 27-36 include the subject matter of claims 1 and 22, respectively, none of Campbell '118, Linscott '557, Cayen '438 or Pegel '603 disclose or suggest the subject matter of claims 6-17 and 27-36.

None of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 supply the deficiencies of Campbell '118, Linscott '557, Cayen '438 or Pegel '603 with respect to claims 1, 6-17, 22 and 27-36. Thus, the combination of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 with Campbell '118, Linscott '557, Cayen '438 and Pegel '603 fails to meet the standard presented by MPEP § 2143 which, as stated above, requires that the combined prior art references must teach or suggest all the claim limitations to establish a prima facie case of obviousness.

Furthermore, MPEP § 2143.01 provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Specifically, Campbell '118 is directed to an animal feed and water additive, Linscott '557 is directed to a granola bar with supplemental dietary fiber, Cayen '438 is directed to compositions for reducing blood cholesterol, Pegel '603 is directed to a sterol glycoside with activity as a prostaglandin synthetase inhibitor, Graves '122 is directed to a process for enhancing the natural bile acid binding capacity of edible pulp material, Balch is a general guide to the bodily function and source of a multitude of vitamins, herbs and food supplements, Policappelli '039 is directed to a dietary supplement composition that includes herbal extracts combined with glucomannan or galactomannan, Morrison '958 is directed to a food supplement that includes soy lecithin and Dohnalek '526 is directed to the use of fructooligosaccharides that occur in plants such as onions, asparagus, and tomatoes to prevent gastrointestinal infections and to reduce duration of diarrhea in humans. Each reference addresses a different matter and one of ordinary skill in the art would have no reason or motivation to combine any of such references, much less all nine of them. Therefore, there is no basis for the combination of Campbell '118, Linscott '557, Cayen '438, Pegel '603, Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526, and it is respectfully submitted that the combination is improper. For the foregoing reasons, it is respectfully requested that the rejection of Claims 1, 6-17, 22 and 27-36 under 35 U.S.C. §103(a) over Campbell '118, Linscott '557,

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Cayen '438 and Pegel '603 in view of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 be withdrawn.

Claims 40-43 stand rejected under 35 U.S.C. §103(a) over Citkowitz in view of New Zealand Patent Publication No. 299,607 to Horiguchi (hereafter Horiguchi '607).

Horiguchi '607 discloses a food product including sea urchin roe mixed with rice flour and/or wheat flour and/or starch.

Contrary to the claimed dietary supplement compositions, however, Horiguchi '607 does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on Horiguchi '607 and Citkowitz for the following reasons.

As discussed above, Citkowitz do not disclose or suggest the subject matter of claim 40. Specifically, Citkowitz does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are bioavailable as monosaccharides. Therefore, since claims 41-43 include the subject matter of claim 40, Citkowitz does not disclose or suggest the subject matter of claims 40-43.

Horiguchi '607 does not supply the deficiencies of Citkowitz with respect to claims 40-43. Thus, the combination of Horiguchi '607 and Citkowitz fails to meet the standard presented by MPEP § 2143 which, as stated above, requires that the combined prior art references must teach or suggest all the claim limitations to establish a prima facie case of obviousness.

Furthermore, MPEP § 2143.01 provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Specifically, Citkowitz is directed to an analysis of the hyaline layer of sea urchin embryos and Horiguchi '607 is directed to a food product including sea urchin roe mixed with rice flour and/or wheat flour and/or starch. Each reference addresses a different matter and one of ordinary skill in the art would have no reason or



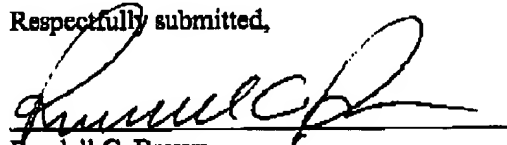
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motivation to combine such references. Therefore, there is no basis for the combination of Citkowitz and Horiguchi '607, and it is respectfully submitted that the combination is improper. For the foregoing reasons, it is respectfully requested that the rejection of Claims 40-43 under 35 U.S.C. §103(a) over Citkowitz and Horiguchi '607 be withdrawn.

For all of the foregoing reason, it is respectfully submitted that claims 1, 6-17, 22, 27-36 and 40-43 are in condition for allowance. Favorable reconsideration and allowance of claims 1, 6-17, 22, 27-36 and 40-43 are respectfully requested.

Respectfully submitted,

Date: 9/24/02



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**ATTACHMENT A  
MARKED-UP VERSION**

**In the Claims**

The following claims 1, 6, 22, 34, and 40 are amended as indicated below.

1. (Thrice Amended) A dietary supplement composition [for providing nutritional product saccharides in monomeric, oligomeric or polymeric and derivatized or underivatized form, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement composition] comprising nutritionally effective amounts of at least six saccharides,

wherein at least one of said saccharides [are] is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and

wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan; and

wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides [comprises at least one saccharide selected from said first group of saccharides and at least one saccharide selected from said second group of saccharides].

6. (Thrice Amended) A dietary supplement composition according to claim 1, wherein at least one of said saccharides is [provided in] derived from an oligomeric or polymeric form of saccharides as found in at least one of:

gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

22. (Amended) A dietary supplement composition [for providing nutritional product saccharides in monomeric, oligomeric or polymeric and derivatized or underivatized form, which

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saccharides are essential components of glycoproteins in a mammal, said dietary supplement composition] comprising nutritionally effective amounts of at least six saccharides,

wherein at least one of said saccharides [are] is selected from a first group of saccharides consisting of: galactose, glucose, mannose and xylose; and

wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid and iduronic acid; and

wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides [comprises at least one saccharide selected from said first group of saccharides and at least one saccharide selected from said second group of saccharides].

34. (Amended) A dietary supplement composition according to claim 1, further comprising an herbal extract or plant extract of broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple[.], tomato, asparagus, mushroom, parsnip, radish and turnip.

40. (Amended) A dietary supplement composition [for providing nutritional product saccharides, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement] comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose;

wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides.

## TECHNICAL INFORMATION



### WATER SOLUBLE GUMS

**W**ater. Just as water is essential to life, so too is water control essential to the formulation of food and non-food products. Water and its behavior are critical to the success of baked goods, beverages, candy, cheeses, flavor encapsulation, ice creams, icings, meat products, salad dressings, and sauces. Non food products in which water control is critical to success include: air freshener gels, dental impression molds, bacteriological test media, drilling muds, hand creams, herbicides, lithography solutions and toothpaste. The lists are endless and new applications are constantly being developed.

Water Soluble Gums have a myriad of functions. Among these are: agglomeration aids, encapsulation agents, coating agents, emulsification, gelling agents, stabilizers, moisture retainers, thickeners, and bulking agents. Gums are used to improve mouthfeel and pourability, extend shelf-life, encapsulate flavors, emulsify beverages, build viscosity, retain moisture, provide elasticity and freeze-thaw stability. They also control meltdown of frozen fruit toppings.

Food manufacturers have a renewed interest in Water Soluble Gums as consumers are increasingly health conscious. Low calorie and high fiber is in. Fats are out. Gums do not metabolize in the body and thus do not add to the caloric count. They provide bulk and control mouthfeel and texture of food products. Gums combine with relatively large volumes of water thus enabling low calorie foods to impart a senso of fullness. The high soluble dietary fiber of gums contributes to good health.

Water Soluble Gums are derived from a variety of botanical sources including tree exudates (Arabic, Ghatti, Karaya, Shiraz, Talha and Tragacanth), seeds (Locust-Carob-Bean and Guar), seaweeds by extraction (Agar, Alginate, Carrageenan, Furcelleran, Propylene Glycol Alginate and Sodium Alginate) and beet sugar by fermentation (Xanthan).

Clearly there is a wide choice. It is important to know the intended use and sometimes the combination of ingredients being used with the gum and manufacturing conditions to select the right gum. Often one gum by itself doesn't do the job. Gum combinations, such as our Merecol® Specialty Stabilizers, utilize the various properties of the different gums.

Frutarom Inc. has the broadest range of Water Soluble Gums in the industry. Our technical staff is available to assist you in the selection of the gum or stabilizer that will work for you.

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